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February 9, 2004

Office of Nutritional Products Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Pkwy College Park, MD 20740

Re: Notification for Statements on Dietary Supplement Labels

Dear Sir/Madam:

This firm represents Synergy Worldwide, Orem, Utah, a distributor of dietary supplement products (hereafter "Synergy"). Synergy has requested that we notify your Agency on its behalf of the inclusion of statements of nutritional support on a dietary supplement product label.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Synergy has made statements of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for a dietary supplement as follows:

## **Product Name**

## Label Statement(s)

Calcium Plus

Structural support. Help maintain proper bone structure and function. It combines the optimal blend of nutrients that years of research have shown to be most important for bone health.

Two copies of this notification are enclosed with this original document.

975 0162 LET 13823

The undersigned hereby certifies on behalf of Synergy that the information contained in this correspondence is complete and accurate.

Sincerely yours,

**GRONEK & ARMSTRONG** 

Robert E. Armstrong

REA:

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**Enclosures** 

CC: Synergy Worldwide